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10/596,566	06/16/2006	Francis Ignatious	PU60627	7929

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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

NOTIFICATION DATE	DELIVERY MODE
12/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,566	IGNATIOUS ET AL.	
	Examiner	Art Unit	
	BRANDON J. FETTEROLF	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/08/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Election filed on November 10/10/2008 in response to the Restriction Requirement of 6/24/2008 has been entered. Applicant's election, without traverse, of Group I, claims 1-12, as specifically drawn to the special technical feature of a complex of an amphiphilic copolymer with a bioactive agent, wherein the amphiphilic copolymer has a benzoyl sulfonic acid group on the hydrophobic segment of said copolymer and a method of treating cancer comprising administering an effective amount of the complex to a patient in need has been acknowledged. Applicants have further elected the following species:

a) carboxymethyl cellulose from claim 3;

b) polyethylene glycol as recited in claim 6 for the species election of Claim 5; and

c) polylactic acid as recited in claim 9, for the species election of claim 8.

Upon careful review and reconsideration, the species election from claim 3 is withdrawn. Thus, in view of the election being without traverse, the restriction requirement is therefore deemed to be proper and is made FINAL.

Claims 1-16 are currently pending.

Claims 13-16 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-12 are under consideration.

Information Disclosure Statement

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references

cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

The Information Disclosure Statement filed 7/08/2008 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Specification

The disclosure is objected to because of the following informalities: The specification does not appear to have separate section describing the drawings.

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S.

patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an

abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Appropriate correction is required.

Applicants are reminded that no new matter should be introduced by amendment to the specification, see MPEP 35 USC 132.

Claim Objections

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 which depends from claim 5 recites polyethylene glycol as the hydrophobic polymer. However, claim 5, from which claim 6 depends, does not appear to recite polyethylene glycol or a "genus of" polyalkyl ethers. As such, it is unclear how the recitation of polyethylene glycol further limits claim 5. For examination purposes, claim 5 will be examined as if it recited polyethylene glycol.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al .(WO 01/87345 A1, 2001) in view of Cho et al .(WO 2004/022036 A1, 2004, filed on 5/30/2003).

Seo et al. teach a stable biodegradable polymer micelle-type drug composition which comprises: a modified biodegradable polymeric drug carrier micelle having a hydrophobic drug physically trapped within, wherein the drug carrier comprises an amphiphilic block copolymer having a hydrophilic poly(alkylene glycol) A block component, and a biodegradable hydrophobic polymer B block component selected from the group consisting of poly(lactic acid), poly(glycolic acid) and poly (lactic co-glycolic acid), and wherein the amphiphilic block copolymer has terminal ends modified with end groups that have an attraction or affinity for the hydrophobic drug contained in the micelle core (page 5, lines 7-17). With regards to the hydrophilic poly(alkylene glycol), the WO document teaches that hydrophilic poly(alkylene glycol) include, but are not limited to, polyethylene glycol within the range of 1,000 to 15,000 daltons (page 6, lines 17-23). With regards to the end groups, the WO document teaches that the hydrophobic polymers are capped with an end group such as a benzoyl group (page 9, lines 9-16). With regards to the hydrophobic drug, the WO document teaches that hydrophobic drugs include, but are not limited to, doxorubicin and cisplatin (page 8, lines 2-5).

Seo et al. do not explicitly teach that the hydrophobic polymer comprising a benzoyl end group further comprises a sulfonic acid.

Cho et al. teach amphiphilic block copolymers comprising hydrophobic blocks and hydrophilic blocks, wherein the hydrophobic block comprises a sulfonic acid which enhances the core's affinity to a water-insoluble drug (page 2, line 29 to page 3, line 8).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to modify the hydophobic polymer taught by Seo et al .to further comprise a sulfonic acid in view of the teachings of Cho et al. One would have been motivated to do so because as taught by Cho et al .the addition of sulfonic acid to hydrophobic block polymers enhances the core's affinity to water-insoluble drugs. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by modifying the hydophobic polymer taught by Seo et al .to further comprise a sulfonic acid in view of the teachings of Cho et al, one would further enhance the affinity to water-insoluble drugs.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al .(WO 01/87345 A1, 2001) in view of Cho et al .(WO 2004/022036 A1, 2004, filed on 5/30/2003), as applied to claim 1-10, in further view of Giovanella et al. (2002/0107260, 2002)..

Seo et al. in view of Cho et al .teach a stable biodegradable polymer micelle-type drug composition which comprises: a modified biodegradable polymeric drug carrier micelle having a hydrophobic drug physically trapped within, wherein the drug carrier comprises an amphiphilic block copolymer having a hydrophilic poly(alkylene glycol) A block component, and a biodegradable hydrophobic polymer B block component selected from the group consisting of poly(lactic acid), poly(glycolic acid) and poly (lactic co-glycolic acid), and wherein the amphiphilic block copolymer has terminal ends modified with an end group comprising a benzoyl sulfonic acid. With regards to the hydrophobic drug, the WO document teaches that hydrophobic drugs include, but are not limited to, doxorubicin and cisplatin (page 8, lines 2-5 of Seo et al.). Moreover, Seo et al. teach that the biodegradable polymer micelle-type drug composition has minimal side effects and shows improved bioavailability (abstract).

Seo et al. in view of Cho et al .do not explicitly teach that the hydrophobic drug is topotecan or a a method of treating cancer comprising administering an effective amount of the complex to a patient in need thereof.

Giovanella et al. teach a method of treating a tumor in a mammal comprising administering to said mammal a water-insoluble compound, wherein the water-insoluble compound includes, but is not limited to topotecan (claim 1 of the publication). Cho et al. teach amphiphilic block copolymers comprising hydrophobic blocks and hydrophilic blocks, wherein the hydrophobic block comprises a sulfonic acid which enhances the core's affinity to a water-insoluble drug (page 2, line 29 to page 3, line 8).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to substitute the hydrophobic drugs as taught by Seo et al .in view of Cho et al .for topotecan in view of the teachings of Giovanella et al. One would have been motivated to do so because as taught by Giovanella et al., topotecan is a water-insoluble drug. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by substituting the hydrophobic drugs as taught by Seo et al .in view of

Cho et al .for topotecan in view of the teachings of Giovanella et al., one would achieve a suitable delivery means for water-insoluble topotecan.

Additionally, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer the biodegradable polymer micelle-type drug composition as taught by Seo et al .in view of Cho et al .to a patient suffering from cancer in view fo the teachings of Giovanella et al. One would have been motivated to do so because as taught by Seo et al., the biodegradable polymer micelle-type drug composition comprising chemotherapeutic agents has minimal side effects and shows improved bioavailability Thus, one of ordinary skill in the art would have a reasonable expectation of success that by administering the biodegradable polymer micelle-type drug composition as taught by Seo et al .in view of Cho et al .to a patient suffering from cancer in view of the teachings of Giovanella et al., one would achieve improved bioavailability of the drug.

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf
Primary Examiner
Art Unit 1642

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642